STATE AND CONSUMER SERVICES AGENCY DEPARTMENT OF CONSUMER AFFAIRS ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF MEETING and AGENDA Communication and Public Education Committee

Time: 10 a.m. – 12 noon Date: March 26, 2004

Place: Department of Consumer Affairs

400 R Street, Suite 4080, Sacramento, CA 95814

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at (916) 445-5014, at least five working days before the meeting. Candy Place can also provide further information prior to the meeting and can be contacted at the telephone number and address set forth above.

This notice is posted at www.pharmacy.ca.gov.

Opportunities are provided for public comment on each agenda item.

MEETING AGENDA

- A. Call to Order
- B. Update and Discussion: Public Education and Communication Plans
 - Work with Schools of Pharmacy/Pharmacist Interns to Develop New Fact Sheet Series for Public Education
 - 2. Development of Public Information on the New Federal Medicare Drug Discount Program
- C. Development of Internet Subscriber Lists for Board Materials
- D. Discussion of Planned Activities to Fulfill Strategic Goals Update Report
 - 1. Status of *The Script*
 - 2. Discussion: Health Notes Publication Plans for the Future
 - 3. Emergency Contraception Fact Sheet
- E. Review and Comment: New Consumer Brochure from the Federal Food and Drug Administration on "The best way to take your over-the counter pain reliever? Seriously."
- F. Update on the Board's Public Outreach Activities
- G. Proposed Modifications to the Committee's Strategic Plan
- H. Adjournment 12 noon

Agenda Item B

Development of Public Education Materials

Memorandum

To: Communication and Public Education Committee Date: March 12, 2004

From: Board of Pharmacy – Virginia Herold

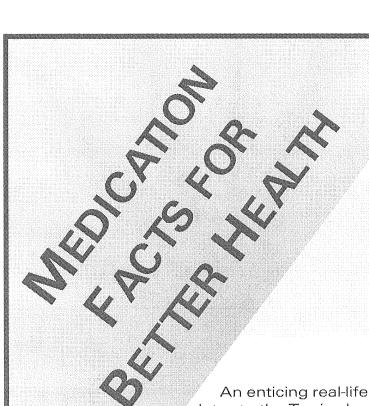
Subject: Development of Fact Sheet Series for Consumers

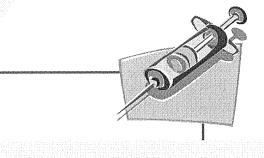
Since the fall of 2003, the newly structured Communication and Public Education Committee has sought creative ways to integrate pharmacy students into public outreach activities. By so doing students can share their knowledge and enthusiasm with patients.

At this meeting, the committee needs to discuss and refine a proposal initiated at the last meeting.

The proposal is for pharmacist interns to develop new public education materials on specific topics the students learn about during their internships or classes, or topics that are emerging public policy matters (e.g., flu vaccines: inhalation forms vs. shots). If we develop a prototype format for a series of fact sheets, each student could complete the information and be acknowledged with a credit at the bottom of the fact sheet. This would benefit the resumes of those students who prepare the fact sheets, and via the availability of the information, the public and the board would benefit. The standardized format would make it easy for students and the board to develop and produce, and easy for the public to reference.

A sample fact sheet follows.





TOPIC: Flu Vaccines

ANECDOTAL SITUATION:

An enticing real-life hypothetical situation provided here that relates to the Topic above. Include in discussion a description of the impact on the patient if left untreated.

FACTS PATIENTS SHOULD KNOW:

Information provided on the topic here. For example, discussion surrounding the importance of flu vaccines in the prevention of contacting various flu strains that could result in death.

KEY POINTS FOR PATIENT HEALTH

- ✓ Key Point #1
- ✓ Key Point #2
- ✓ Key Point #3
- ✓ Key Point #4
- ✓ Key Point #5
- ✓ Key Point #6

For additional resources, you may want to check:

This fact sheet is one in a series prepared for the public so they can better safeguard their health and make informed health care decisions.

Memorandum

To: Communication and Public Education Committee Date: March 12, 2004

From: Board of Pharmacy – Virginia Herold

Subject: Development of Consumer Information on the Medicare Prescription Drug

Discount Program and Discount Card

Board President John Jones would like the board to develop consumer information about the new federal Medicare Prescription Drug, Improvement and Modernization Act of 2003. This is a complex piece of legislation that is nearly 700 pages in length.

This act will provide Medicare beneficiaries with discounts on their prescription drugs as well as provide comprehensive Medicare prescription drug coverage effective January 1, 2006. Starting in May 2004, Medicare beneficiaries will be able to enroll in a Medicare-approved discount card program (The Discount Card) that will offer discounts on prescription drugs.

The federal government has produced some consumer information on this program on their Web site www.cms.hhs.gov. or www.medicare.gov. I am enclosing copies of some this material.

The committee needs to determine what types of materials it should develop in this area.

As one option, I will prepare and bring to the meeting a one-page referral sheet of Web site addresses referencing the federal government's online resources for the public in this area.

The committee may come up with additional ideas.



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Learn more about the Medicare Modernization Act (MMA) Frequently Asked Questions on Charges For The Uninsured: Microsoft Word (39 KB) | Adobe PDF (103 KB)

Headlines Current Interest Current Publications Resources

- MMA Contracting Reform Information Now Available
- *Fact Sheet: Federal Payment Methodology to Medicare Health Plans
- *CMS and Partners Announce FirstStep Tool to Help Assist People Who Are Homeless
- 🏂 Press Release: Review Shows Beneficiaries in Medicare Advantage Plans Will See Better Benefits, Lower Costs
- CMS Announces the Release of the Medicare Modernization Update (MMU)
- *Press Release: CMS Urges States to Adopt Disease Management Programs, Agency Will Match State Costs
- *"The Right Answer" Medicare Modernization Act Ad Campaign
- *Press Release: CMS Announces Significant Increase in Numbers of Hospitals Voluntarily Reporting Hospital Quality Data
- CMS Announces Revisions to the Notice of One-Time Appeal Process for Hospital Wage Index Classification
- *Press Release: 2003 Expected to Mark First Slowdown in Health Care Cost Growth in Six Years

Previous Headlines



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Medicare Modernization Act

On December 8, 2003, President George W. Bush signed into law the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003. This landmark legislation provides seniors and people living with disabilities with a prescription drug benefit, more choices and better benefits under Medicare, the most significant improvement to senior health care in nearly 40 years.

This page will be frequently updated with information over the next several months as CMS begins implementation of these benefits and reforms.

Information on CMS Implementation of the Medicare Prescription Drug, Improvement and Modernization Act of 2003

Medicare Prescription Drug Discount Card and Transitional Assistance Program

- General Information and Resources
- Information for Drug Card Sponsors

Contracting Reform

General Medicare Reform Information

- Beneficiary Information (medicare.gov)
- Frequently Asked Questions
 - o Medicare Reform
 - o Drug Card
 - o Beneficiary
- Issue of the Day
- Issue Papers (Coming Soon)
- Medicare Modernization Update NEW
- "The Right Answer" Ad Campaign NEW

Other Resources

- Full Text of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (PDF, 1.1 MB)
- HHS Press Release: <u>HHS Announces Immediate Steps to Make</u>
 <u>Medicare-Approved Drug Discount Card Programs Available Next Spring</u>
- White House Press Release: President Signs Medicare Legislation

Note: Some of the files on this page are available only in Adobe Acrobat - Portable Document Format (PDF). To view PDF files, you must have the Adobe Acrobat Reader (minimum version 4, version 5 suggested). You can <u>check here</u> to see if you have the Acrobat Reader installed on your computer. If you do not already have the Acrobat Reader installed, please go to Adobe's <u>Acrobat download page</u> now.

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Medicare-Approved Prescription Drug Discount Card Program

On December 8, 2003, President George W. Bush signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003. This act will immediately provide Medicare beneficiaries with discounts on their prescription drugs as well as provide comprehensive Medicare prescription drug coverage effective January 1, 2006.

Starting in the Spring of 2004, as an important first step towards comprehensive Medicare prescription drug coverage, Medicare beneficiaries will be able to enroll in a Medicare-approved discount card program (The Discount Card) that will offer discounts on their prescription drugs. If your Medicare patients raise questions about the Discount Card, you should suggest they visit www.medicare.gov and select "Prescription Drug and Other Assistance Programs" or call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-800-486-2048.

This site will be updated as new information becomes available so check back often and book mark this site for quick access.

NOTE: Information for potential Medicare Prescription Drug Discount Card sponsors can be found at http://www.cms.hhs.gov/discountdrugs/.

Highlights

Quick Facts About The Discount Card

- The Discount Card is a new important first step toward a prescription drug benefit for Medicare beneficiaries. The Discount Card is not a comprehensive Medicare prescription drug benefit.
- The Discount Card is a voluntary program and is slated to begin six months after the Medicare Reform bill is signed into law.
- The Discount Card is intended as a temporary program to provide immediate assistance in lowering prescription drug costs for Medicare beneficiaries during 2004 and 2005 and will end when Medicare implements a new, comprehensive prescription drug benefit that will begin January 1, 2006.
- The Discount Card is designed to provide Medicare beneficiaries access to discounts on their prescription drugs through enrollment in card programs offered by sponsors approved by Medicare.
- All Medicare beneficiaries are eligible for The Discount Card, except for those who have Medicaid drug coverage.

- Certain enrollees may also qualify for as much as \$600 to help them pay for prescription drugs. Eligibility for this assistance will be based on a beneficiary's income and whether he or she already has any other prescription drug coverage.
- The Discount Card is only one of a number of programs available to help Medicare beneficiaries receive discounts on the price of their prescription drugs.
- Discount cards that are approved by Medicare will display a Medicareapproved mark on the card.

Resources

medicare.gov: Can I get a new Medicare-Approved Drug Discount Card?

HHS Overview of Medicare Prescription Drug Discount Card and Transitional Assitance Program

Press Releases Regarding the Medicare Prescription Drug Card

- <u>December 10, 2003 News Release</u>, "HHS Announces Immediate Steps to Make Medicare-Approved Drug Discount Card Programs Available Next Spring"
- November 25, 2003 News Release, "Secretary Thompson Applauds Final Passage of Medicare Bill"
- November 24, 2003 News Release, "Savings for Seniors Under The Medicare Prescription Drug Benefit"
- November 22, 2003 News Release, "Statement by Tommy G.
 Thompson Secretary of Health and Human Services On House
 Passage of Bipartisan Medicare Legislation"
- November 21, 2003 News Release, "21st Century Medicare: More Choices Better Benefits"

Frequently Asked Questions

- Medicare Reform
- Drug Card
- Beneficiary

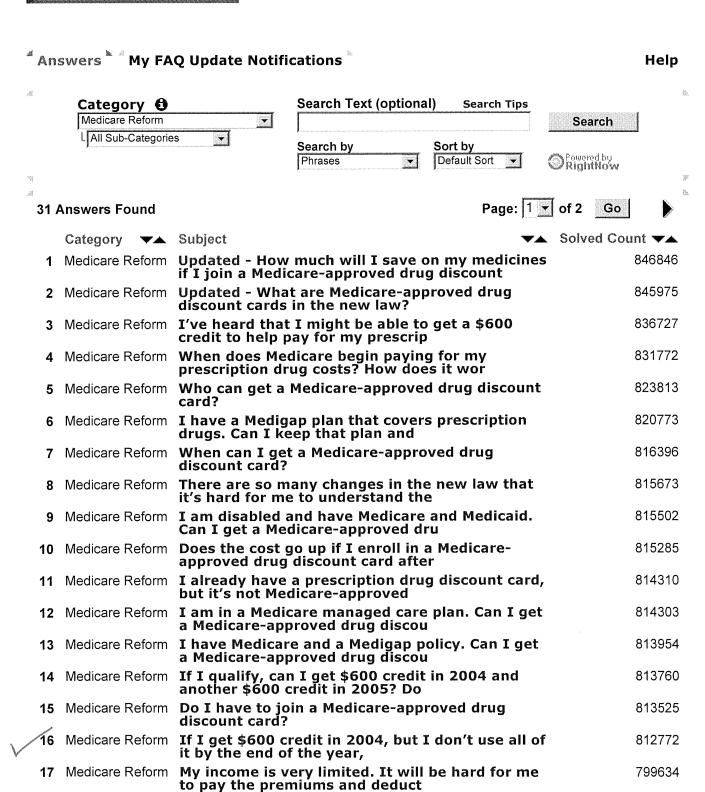
Prescription Drug and Other Assistance Programs

This section of Medicare.gov provides information on public and private programs that offer discounted or free medication, programs that provide assistance with other health care costs, and Medicare health plans that include prescription coverage.

Note: Some of the files on this page are available only in Adobe Acrobat - Portable Document Format (PDF). To view PDF files, you must have the Adobe Acrobat Reader (minimum version 4, version 5 suggested). You can <u>check here</u> to see if you have the Acrobat Reader installed on your computer. If you do not already have the Acrobat Reader installed, please go to Adobe's Acrobat download page now.

Last Modified on Tuesday, December 23, 2003

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18	Medicare Reform	What is the new law and how will it affect me?	797618
19	Medicare Reform	Where can I go for the latest, official information about changes in Medicare?	797586
20	Medicare Reform	Does the new law make any changes to Medigap supplement policies?	789185

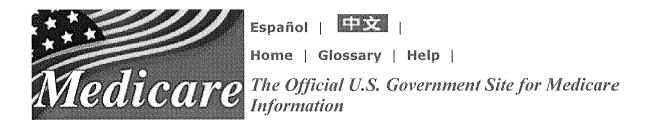
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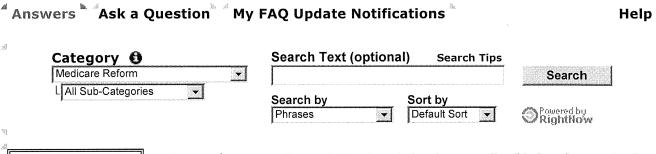
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Answer Page 1 of 2





Answer ID
1494

Category
Coverage
Medicare Reform
Drug Card
Prescription Drugs

Date Created
12/23/2003 11:23 PM

Date Updated
02/10/2004 03:07 PM



a Friend

If I get \$600 credit in 2004, but I don't use all of it by the end of the year, do I lose it? Can I carry the extra money over and use it in 2005?

Question

If I get \$600 credit in 2004, but I don't use all of it by the end of the year, do I lose it? Can I carry the extra money over and use it in 2005?

Answer

If you keep the same Medicare-approved drug discount card and some of your \$600 credit is left at the end of 2004, you can use that money in 2005. You don't have to reapply for the \$600 credit to help pay for your prescriptions in 2005.

Please look at our new tool to see if you can get a new **Medicare-approved drug discount card** .

Notify Me by E-mail if this Answer is Updated

How well did this answer your question?

O Very Helpful O Somewhat Helpful O Not Helpful Submit Rating

Related Answers

- If I qualify, can I get \$600 credit in 2004 and another \$600 credit in 2005? Does it matter when I enroll?
- I am in a Medicare managed care plan. Can I get a Medicareapproved drug discount card?
- I have Medicare and a Medigap policy. Can I get a Medicareapproved drug discount card, and how will it affect my Medigap coverage?
- I am disabled and have Medicare and Medicaid. Can I get a Medicare-approved drug discount card?

Page 2 of 2 Answer

• Do I have to join a Medicare-approved drug discount card?

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Medicare-Approved Drug Discount Cards

Starting in 2004, Medicare-approved drug discount cards will be available for immediate savings on prescription drugs. Medicare will contract with private companies to offer new, voluntary drug discount cards. A Medicare-approved drug discount card offers a discount off the full retail price of prescriptions. Savings are estimated to be 10-25% on many drugs. These voluntary cards are being offered until December 31, 2005, when this program ends and the new comprehensive prescription drug benefit begins.

If your income is no more than \$12,569 as a single person, or no more than \$16,862 for a married couple, you might qualify for a \$600 credit to help pay for your prescription drugs. If you qualify, Medicare will put a \$600 credit on your Medicare-approved drug discount card that you can use when you get your prescriptions. You won't have to pay the annual enrollment fee for the discount card if you qualify for the \$600.

To find out if you can get a Medicare-Approved Drug Discount Card and if you qualify for the \$600 credit to help pay for prescription drugs, answer the following questions:

<u>Q</u> uestions	
1. Do you have Medicare?	select one ▼
2. Do you have any of the following? Help	Outpatient prescription drug benefits under your State Medicaid Program (your state may call this Medical Assistance) TRICARE (military health insurance) FEHBP (health insurance for Federal employees or retirees) Other health coverage that includes prescription drugs, such as employer or retiree plans None of the above





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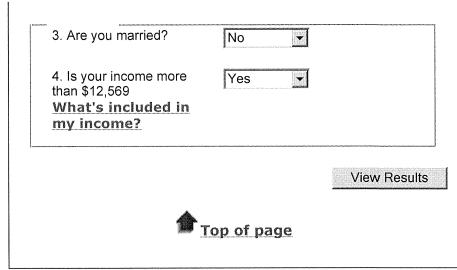
Medicare-Approved Drug Discount Cards

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<u>Q</u> uestions	
1. Do you have Medicare?	Yes ▼
2. Do you have any of the following? Help	Outpatient prescription drug benefits under your State Medicaid Program (your state may call this Medical Assistance) TRICARE (military health insurance) FEHBP (health insurance for Federal employees or retirees) Other health coverage that includes prescription drugs, such as employer or retiree plans None of the above







116



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Results

You are eligible to enroll in a Medicare-approved drug discount card. Because you indicated that your income is more than \$12,569 (if single) or \$16,862 (if married), you will not be eligible for the \$600 credit but you may be able to save money on your prescription drugs by enrolling in a Medicare-approved drug discount card.

Where to get more information

In spring of 2004, you will be able to get more information on Medicare-approved drug discount cards by:

- Visiting the <u>Prescription Drug and Other</u>
 Assistance <u>Programs</u> section of the web site.
- Calling 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.
- Calling your <u>State Health Insurance Assistance</u> **Program** counselor.

Visit Frequently Asked Questions now.



Centers for Medicare & Medicaid Services



Department of Health and Human Services

116

Agenda Item C

Development of Internet Subscriber Lists for Board Materials

Memorandum

To: Communication and Public Education Committee Date: March 12, 2004

From: Board of Pharmacy – Virginia Herold

Subject: Creation of E-Mail Subscriber Lists

Since the January committee meeting, staff has been researching a way to set up a subscriber list on the board's Web site. This feature would send e-mails to interested parties announcing that the board's Web site has been updated. The interested parties would subscribe themselves to the board's Web site, and be responsible for keeping their e-mail addresses current.

If implemented, this service has the potential to substantially reduce the board's mailing expenses as well as printing costs. Materials that we currently publish and mail could be sent without cost via e-mail. It also would allow the board to update licensees far more quickly about new information and laws.

The department's Office of Information Services has identified two software programs that could permit the board to establish such a subscriber list.

The board will purchase and install software program and start a trial for this before the end of fiscal year.

Agenda Item D

Discussion of Planned Activities to Fulfill Strategic Goals

- 1. Status of the The Script
- 2. Health Notes
- 3. Emergency Contraception Factsheets

Memorandum

To: Communication and Public Education Date: March 10, 2004

Committee

From: Virginia Herold

Assistant Executive Officer

Subject: Update: The Script

The board's next newsletter to licensees, *The Script* (March 2004 issue), is currently at the State Printing Plant. This issue will focus on the many substantial changes to pharmacy law that will take effect in 2004 (e.g., changes in the prescribing and dispensing of controlled substances, new pharmacy technician requirements, new pharmacist licensure examinations).

The board should mail this issue by the end of March or early April to all pharmacies. The CPhA's Education Foundation will again fund the much larger printing and mailing of the newsletter to all California pharmacists.

Each of the last three issues of *The Script* have been published and mailed under such a collaborative arrangement with CPhA. In November, the CPhA mailed the October 2003 issue to all pharmacists. This is a significant partnership for us, and we are grateful for this assistance.

The board's next newsletter will be written and published this summer. The board's newsletter is a key strategic objective of the board, and is board's principal means of communication with licensees.

The costs for the March issue will be more than those for the October 2003 issue (which was approximately \$15,000):

 Newsletter Editor:
 \$ 3,000

 Printing:
 \$12,000

 Postage:
 \$ 2,000

 \$17,667

To reduce printing and postage costs, the board prints enough newsletters to mail to all pharmacies (about 6,000 sites), and produces additional copies for casual distribution from the board's office or during outreach events. The newsletter is immediately placed on the board's Web site for anyone to access it. Formerly, the board mailed the newsletter to all pharmacists and interns, which would be another 32,000 copies.

Memorandum

To: Communication and Public Education Committee Date: March 10, 2004

From: Board of Pharmacy – Virginia Herold

Subject: Health Notes Planning Schedule

Health Notes is a monograph, produced by the board, that contains up-to-date drug therapy guidelines for a specific subject area. Because Health Notes is produced by the board, it conveys what the board believes is current drug treatment in a particular area. Pharmacists can earn continuing education credit by completing a test published at the back of the monograph. Thus the board provides education and actually is sponsoring CE in an area of importance to the board.

Health Notes was developed during the mid1990s by the board. Typically it is produced via contract with recognized experts (often UCSF) who identify qualified authors, provide technical editing and coordination services, leaving the board to executively edit the articles and coordinate distribution of the published copies. A graphic artist does the layout and works with the board and the coordinator of the issue.

Typically one issued is published annually. Total costs for development, printing and mailing to all pharmacists are about \$100,000 per issue. The last issue we published was in April of 2003. The board paid for the graphic artist and for postage (about \$35,000); funding for development and printing was paid for by other sources.

Issues Published:

- "Drug Therapy Considerations in Older Adults" April 2003
- "Quality Assurance Programs" September 2002
- "Alternative Medicines" July 2001
- "Care of Children and Adults with Development Disabilities" May 2000
- "Anticoagulation" 1999
- "Women's Health" 1999
- "Pain Management" 1998 & 1996

Future Issues:

1. Pain Management

Staff is now working to publish a wholly new Pain Management issue in mid-2004, probably June. This new issue will contain new pain management therapies and the new prescribing and dispensing requirements for controlled

drugs enacted by SB 151 (Burton, Chapter 406), which will take effect in 2004 through 2005 in sequential stages.

Staff is coordinating the development of this issue. Authors have written articles which are undergoing review and edits. The board will also review the articles (Ken Schell has agreed to do this), as will our Legal Office. The same graphic designer who has designed all other *Health Notes* is available to layout the issue.

The board is seeking outside funding sources for producing this issue. Because of the interest in pain management and in the new changes to prescribing of controlled substances, there is much interest and support for this issue.

We intend to develop an issue that will be of interest also to physicians, nurse practitioners, dentists and other prescribers. Patients who suffer from pain will also be able to use information provided in the issue to obtain improved treatment.

2. UCSF Proposal for Issue on Atrial Fibrilation

The UCSF School of Pharmacy wishes to work with the board to produce a *Heath Notes* on Atrial Fibrilation (afib). The audience would be pharmacists and physicians. Funding for this issue would come from a drug manufacturer. The articles for this issue would include:

- 1. A description of Afib
- 2. A description of risk factors
- 3. A description of signs and symptoms
- 4. Diagnosis tools
- 5. Potential consequences of Afib
- 6. Treatment (medications and other treatments), side effects duration of treatment, influence on other diseases
- 7. Future for "cure"

At this meeting, representatives of UCSF will attend to discuss this request. One suggestion is that in place of publishing this issue as a printed monograph, that instead the issue be placed on the Web site for downloading.

The committee will a have an opportunity to explore this proposal with the UCSF representatives, and its attendant costs and workload on the board's staff. A timeline for development will also need to be created if the committee (and the board) approves the project.

3. Smoking Cessation

Representatives from the UCSF School of Pharmacy will attend the meeting to propose a joint project to develop smoking cessation materials, possibly as a *Health Notes*, or perhaps as an online continuing education program for pharmacists. UCSF in this case would like the board's financial support to develop these materials and to collaborate on distributing them. The representatives are interested in exploring this as a possible project.

The committee will have an opportunity during the meeting to determine if it wishes to recommend the board proceed with this type of project and what type of project it would recommend.

4. Additional Issues

Development and distribution of *Health Notes* is expensive, and the board's budget may not be able to withstand continued development of this monograph until economic conditions improve.

In prior years, the Communication and Public Education Committee had plans to development future issues on additional topics if funding and staffing were available. These topics are:

- "Pediatrics"
- "The 10 Most Frequent Drug Therapies in Community Pharmacy Settings"
- "Pharmacists' Care Protocols"
- a revised "Women's Health" to reflect changes in hormone replacement therapy

Memorandum

To: Communication and Public Education Committee Date: March 12, 2004

From: Board of Pharmacy – Virginia Herold

Subject: Emergency Contraception Fact Sheet

Since the last board meeting, eight translations of the emergency contraception fact sheet prepared by the Pharmacy Access Partnership have been added to the board's Web site.

I am also enclosing the results of a survey by Kaiser Family Foundation that indicates that 91 percent of the women aged 15 to 44 years do not know that emergency contraception is available.



Paul Riches 02/19/2004 12:22 PM

To: RArell10@dhs.ca.gov@DCANotes, Virginia
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cc: ruth.conroy@walgreens.com

Subject: fyi

Most Women Do Not Know Emergency Contraception Is Available in California Without Prescription, Report Finds 02/19/2004

About 91% of California women ages 15 to 44 do not know that emergency contraception is available in the state without a prescription, according to a report released Wednesday by the Kaiser Family Foundation, the AP/Contra Costa Times reports. The report was based on telephone interviews with 1,151 California women ages 15 to 44 and had an overall margin of error of 3.2%. A form of EC called Plan B can reduce the chances of pregnancy by as much as 89% if taken within 72 hours of sexual intercourse, according to the AP/Times. The survey found that 49% of women confused Plan B with mifepristone, a prescription drug that induces abortion. "There's a lot of confusion over terminology, and what's surprising is the extent [Plan B] is confused with [mifepristone]," report author Alina Salganicoff said, adding, "They are very different." In addition, about 74% of women said that they supported the use of Plan B when other birth control methods failed, while 18% said that they had moral or religious objections to the use of Plan B, the report found. California is one of five states that permits pharmacists to dispense Plan B without a prescription (Elias, AP/Contra Costa Times, 2/19). A joint meeting of two FDA advisory panels in December voted to recommend that Plan B be sold without a prescription nationwide (California Healthline, 12/17/03). FDA earlier this month delayed for 90 days a decision on the matter, saying that additional information on use of Plan B by women ages 16 and 17 is needed (AP/Contra Costa Times, 2/19). The survey is available online.

Paul Riches, Chief of Legislation and Regulation CA Board of Pharmacy (916) 445-5014 ext. 4016



EMERGENCY CONTRACEPTION IN CALIFORNIA

Findings from a 2003 Kaiser Family Foundation Survey

This report was prepared by

Alina Salganicoff Barbara Wentworth Usha Ranji

THE HENRY J. KAISER FAMILY FOUNDATION

February 2004

INTRODUCTION

The increased availability of emergency contraception -- also known as "morning-after pills" -- has been an important development in the prevention of unintended pregnancy. However, only a small minority of people who could benefit from emergency contraception are aware that it exists and that it is safe, legal, and in some locations, very easily available. Many health care providers, federal and state policy makers, and reproductive rights activists have been engaged in campaigns to improve the public's awareness of emergency contraception.

There have also been many efforts to expand and facilitate its availability through state policies, as well as grassroots and professional outreach and education initiatives. Most recently, the Women's Capital Corporation petitioned the FDA in 2003 to make emergency contraceptive pills available to women "over-the-counter," without a prescription as is currently required. The FDA advisory committees with jurisdiction over reproductive health matters recommended that emergency contraception be made available "over-the-counter," and the final decision of the FDA commissioner is expected to be announced soon.

Against this backdrop of growing interest in emergency contraception, the Kaiser Family Foundation conducted this survey of women and men ages 15 to 44 living in California about their awareness of, attitudes toward, and experience with emergency contraception. California was selected because it is one of a handful of states that allow women to obtain emergency contraceptive pills directly from a pharmacist without needing to have a prescription from her doctor or health care provider, also called "behind-the-counter" access. This survey was conducted approximately one year after the 2002 enactment of this law.¹ California's large and diverse population and history of leadership on reproductive health issues make it an ideal setting to study the extent to which people are aware of and have access to emergency contraception. Despite its state focus, this survey addresses issues of national importance concerning access, knowledge, and experience with emergency contraception.

While women are the direct users of emergency contraception, men play an important role in reducing unintended pregnancies, making it important to understand their familiarity with and attitudes toward emergency contraception. This survey is one of the first that examines men's knowledge and attitudes. This survey also provides insight into teenagers' experiences with emergency contraception, which differ somewhat from those of their adult counterparts.

This report has two major sections. Section I presents survey findings on knowledge of and attitudes towards emergency contraception among Californians of reproductive age. Section II discusses the experiences of Californians in obtaining and using emergency contraceptives. The conclusion summarizes the key survey findings and identifies remaining challenges to increasing public awareness of emergency contraceptives in order to reduce unintended pregnancy.

¹ California State Legislature, SB 1169. Available at http://www.pharmacyaccess.org/CalifECLegis.htm.

Is emergency contraception used in other countries?

Access to emergency contraception in the United States has trailed that of many other nations. Emergency contraception has been available in the commercial market abroad for many years, beginning in 1984 with the United Kingdom's approval of the first dedicated product. Today, such products are available in more than 80 countries and in many, such as the United Kingdom, France, and Switzerland, it is available "over-thecounter",3

What policies have been considered that affect access to emergency contraceptive pills?

As outreach initiatives continue in the U.S., there has also been movement to facilitate access to emergency contraception, particularly at the state and local levels. One of the most active campaigns has been in achieving "behind-the-counter" status. This arrangement essentially allows women to obtain an emergency contraception prescription and pills directly from a pharmacist, without requiring a physician visit or callin prescription. Five states, including California (since January 2002), now allow qualifying pharmacists to dispense emergency contraception under the authority of a standing prescription. Allowing a woman to obtain emergency contraception directly from a pharmacist is meant to reduce barriers that she may encounter in reaching a physician within the short timeframe when emergency contraception is effective.

Emergency contraceptive pills are also an important advancement in preventing pregnancies in cases of rape and sexual assault. Six states now require that emergency room staff provide information about emergency contraception or offer the pills themselves to women who have been sexually assaulted. In California, both pharmacy access and emergency room mandate programs have been adopted and implemented.

On the national level, legislation has been introduced in Congress that would provide funding for major public education campaigns targeted toward the public and the health care community to broadly increase awareness of emergency contraception.⁴ Federal legislation has also been introduced that would require hospitals to provide emergency contraception in cases of sexual assault.5

These efforts notwithstanding, emergency contraception has not been universally embraced. Some pharmacies and pharmacists have been unwilling to dispense or stock emergency contraceptive pills for reasons including religious or moral objections to its use in preventing pregnancy.⁶ In addition, there have been efforts to limit teens' and college students' access to emergency contraceptives by prohibiting school-based health centers from dispensing these pills to students.7

Alan Guttmacher Institute, "Emergency Contraception: Improving Access," Issues in Brief, No. 3, 2003. Available at http://www.agi-usa.org/ pubs/ib_3-03.pdf.

U.S. House of Representatives, H.R. 1812.

⁵ U.S. House of Representatives, H.R. 2527.

⁶ Kaiser Family Foundation, kaisernetwork Daily Reproductive Health Report, "New York City Comptroller Demands Wal-Mart Provide EC," May 14, 2001. Bennett, et al, "Pharmacists knowledge and the difficulty of obtaining emergency contraception," Contraception Vol. 68, 2003, pp. 261-267.

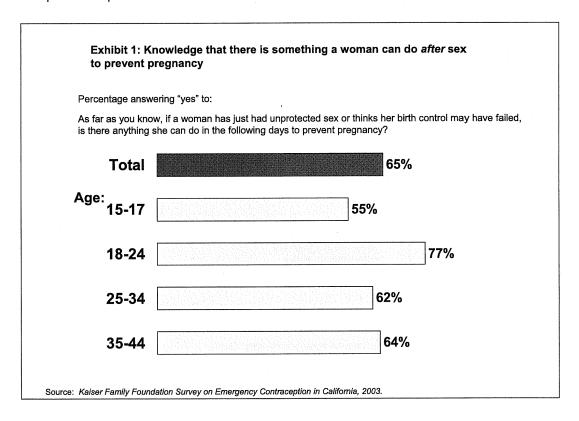
⁷U.S. House of Representatives, H.R. 926, Schoolchildren's Health Protection Act, introduced February 26, 2003. Richmond Times Dispatch, "Did JMU jump gun with ban on sale of pill?" April 25, 2003.

KNOWLEDGE AND ATTITUDES

Two-thirds of Californians of reproductive age know that that there is something a woman can do to prevent pregnancy after birth control failure or unprotected sex.

A majority of teens and adults of reproductive age (65%) correctly respond that there is something a woman can do to prevent pregnancy after contraceptive failure or unprotected sex (Exhibit 1). Still, five years after the FDA approved the first dedicated emergency contraception product, approximately one-third of teens and adults of reproductive age remain unaware of this contraceptive option.

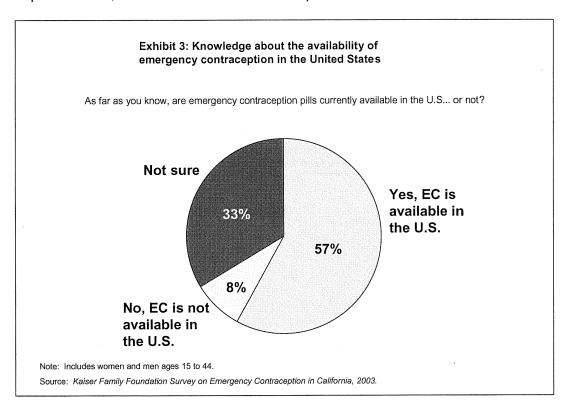
Women are no more likely than men to be aware that there is something a woman can do shortly after sex to prevent pregnancy. Knowledge among teens is slighter lower than for adults. Among those ages 15 to 17, 55% are aware that there is an option compared to 67% for adults. Among adults, however, younger individuals are more likely to be aware of an option compared to older adults.



Knowledge about emergency contraception is limited. Just over half of California teens and adults are aware of emergency contraception's availability in the United States.

While over half of teens and adults of reproductive age (57%) are aware of emergency contraception's availability in the United States, more than 4 in 10 either say that it isn't available here or they are not sure (Exhibit 3). Women (39%) are as likely as men (45%) to be unaware that emergency contraception pills are available in the United States. Nearly half (48%) of teens ages 15 to 17 are unaware that emergency contraception can be obtained in the United States.

Younger adults ages 18 to 24 (76%) are the most likely to report that they are aware that emergency contraception is available here, while adults ages 35 to 44 were the least likely to know that it can be obtained in the U.S. (49%). Even among those who say that they would be likely to take emergency contraception in the case of contraceptive failure or unprotected sex, one-third do not know that the product is available in the United States.

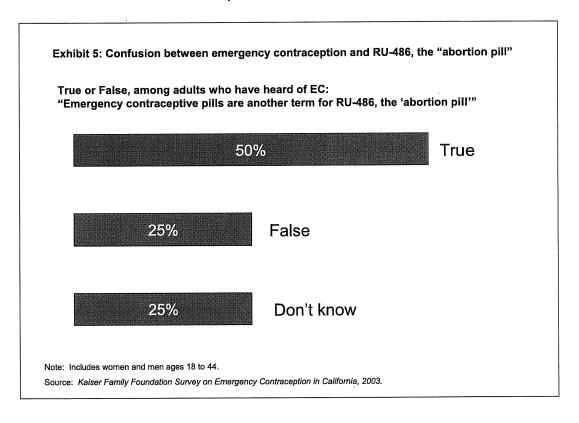


Confusion persists between emergency contraception and "the abortion pill."

Although more than three-quarters of Californians say that they have heard of emergency contraception, there is still considerable confusion about what it actually is. Half of adults who have heard of emergency contraception (50%) state incorrectly that it is another term for RU-486, "the abortion pill" (Exhibit 5). In addition, fully one-quarter (25%) of adults who have heard of emergency contraception report that they do not know if the two are the same. Men and women are equally likely to have this misperception (51% and 49%, respectively) or report that they do not know (24% men vs. 26% women).

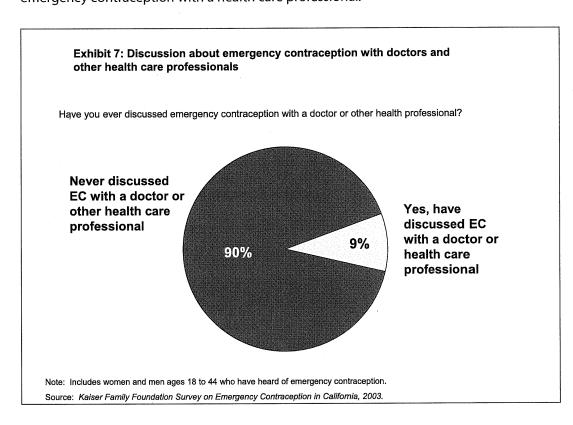
While younger adults are less likely to equate the two compared to older adults, still more than 4 in 10 young adults incorrectly identify emergency contraception as RU-486, or "the abortion pill" (42% among those ages 18 to 24, compared to 53% among those 25 to 44).

When asked if they think that emergency contraception is used primarily to prevent pregnancy, a considerable share of adults who have heard of emergency contraception agree that this is true (73%). Nonetheless, more than a quarter (27%) say that this statement is either false or that they do not know.



Few report that their doctor or health care professional has talked to them about emergency contraception.

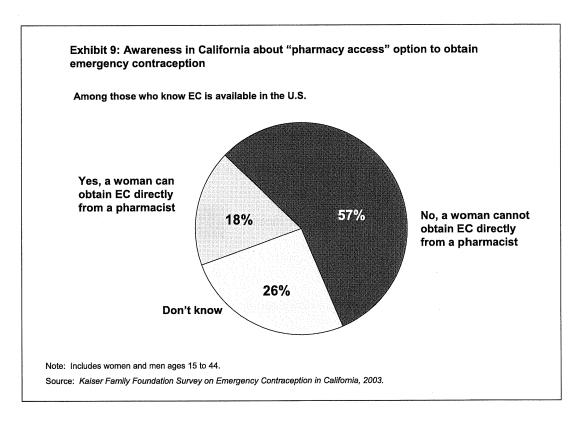
One of the most trusted sources of health information is the physician or health care provider, yet few report that their doctors have discussed this relatively new contraceptive method with them. The overwhelming majority (90%) of adults in California have never discussed emergency contraception with a doctor or other health care professional (Exhibit 7). Among adult women, just 12% report having discussed emergency contraception with a health care professional. This is true even among those who have seen a doctor in the past year. Women who received a gynecological exam in the last year (13%) are no more likely to have discussed emergency contraception with a doctor or other health care professional than women who have not recently received an exam (data not shown). Even among only those who are sexually active, just 10% have discussed emergency contraception with a health care professional.



Most Californians are unaware of the state's "pharmacy access" option.

In 2002, California became one of five states that currently permit women to obtain emergency contraception directly from a pharmacist without first obtaining a prescription from her doctor or clinic. However, few teens and adults of reproductive age in California know about this new policy, which was enacted approximately one year before the survey was conducted. Among the teens and adults who are aware that emergency contraception is available in the United States, just 18% know that women in California can obtain the product directly from a pharmacist without contacting a doctor for a prescription first (Exhibit 9). Therefore, just 9% of California women overall are aware that women have this pharmacy option in cases where emergency contraception is needed.

More than half of teens and adults who know emergency contraception is available in the U.S. (57%) incorrectly state that women cannot obtain emergency contraception directly from a pharmacist, and more than a quarter (26%) say that they don't know. However, these teens are more likely to know about "pharmacy access" in California than adults (29% vs. 18%). Still, fewer than a third of teens are familiar with this option.

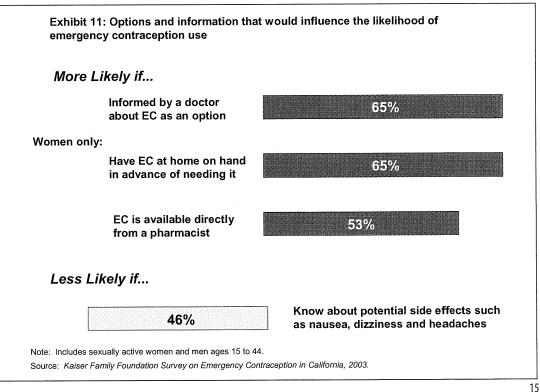


Steps to improve access to emergency contraception such as pharmacy access, advance prescription, and information from a doctor increase the likelihood of emergency contraception use.

Californians say certain factors would affect the likelihood that they would use emergency contraception or recommend it to a partner if needed. Two-thirds of sexually active teens and adults (65%) say that if a doctor informed them about emergency contraception, they would be more likely to take it or recommend it to their partner (Exhibit 11). Teens in particular say that this would affect their intentions, with 87% indicating that a doctor's consultation about emergency contraception would increase the likelihood that they would take it or recommend it to their partner.

Two-thirds of teen girls and women (65%) say that they would be more likely to take emergency contraception to avoid unintended pregnancy if they already had a pack at home in advance of needing it. Over half of teen girls and women (53%) also say that being able to obtain emergency contraception directly from a pharmacist without having to obtain a prescription from a doctor would increase the likelihood that they would take the product.

Ease of access can influence the likelihood of use, even among those who say initially that they would be unlikely to use emergency contraception. For example, among California women of reproductive age who say that they would be unlikely to use emergency contraception, many subsequently report that having it on hand at home (44%) or having it directly available from the pharmacy (31%) would increase their likelihood of taking emergency contraception. Similarly, 40% of teens and adults (both men and women) who say they are unlikely to take or recommend emergency contraception say that hearing a doctor's advice about the option would make them more likely to take it or recommend it to a partner.



Interestingly, teenagers, who typically have the least amount of available income, are more likely than adults to say they would pay higher amounts for emergency contraception. Fully half (50%) of sexually active teens say that they would pay \$40 or more to obtain it.

It is worth noting that a sizable share of the population is unwilling to purchase emergency contraception. Overall, one-fifth (20%) say they would be unwilling to pay for it. (Differences between men and women were not statistically significant.) Only 10% of teens, however, say they would not be willing to buy emergency contraceptive pills.

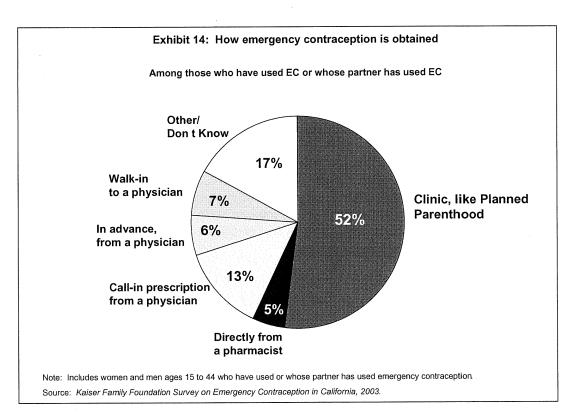
The sample of women in this survey who reported using emergency contraception is too small (37 women) to be analyzed with any statistical precision. While it is difficult to draw conclusions from a sample that is so small, there are some consistent findings among this group that are worth noting.

Of the 37 women in our survey who used emergency contraception, 33 would recommend it to others, suggesting that they had a positive experience with emergency contraception.

Similarly, among a total of 69 individuals who said that they or their partners obtained emergency contraception from a clinic or with a doctor's prescription, 61 men and women say that they did not experience difficulties in obtaining emergency contraception.

Health care clinics are the primary source for obtaining emergency contraception. Receipt directly from pharmacists remains low.

Women turn to a variety of sources to obtain emergency contraception, but health care clinics are the predominant provider. Half of the women (52%) in California who have used emergency contraception obtained the pills from a health care clinic, such as Planned Parenthood. Another 13% report that their physician or their partners' physician phoned in a prescription to a local pharmacy (Exhibit 14).



CONCLUSION

This survey finds that in California, a state that has adopted policies and undertaken significant outreach efforts to promote access to emergency contraception, public knowledge is low – among both men and women -- and experience with emergency contraception is very limited. About two-thirds of Californians of reproductive age know that there is something available to reduce the risk of unintended pregnancy after intercourse. While over three-quarters have heard of emergency contraception or "morning-after pills," many of these people are only familiar with the term and do not know what it does. In addition, there is still major confusion between emergency contraceptive pills -- which prevent pregnancy -- and the abortion pill -- which terminates early pregnancies.

Since January 2002, California law has permitted individuals to obtain emergency contraception from a pharmacy without a doctor's prescription, sometimes called "behind-the-counter" access. Still, only a small minority of Californians know about this option and even fewer have ever used it. This may be due, in large part, to lack of awareness about emergency contraception in general. In addition, when we fielded this survey in the late spring of 2003, this program had only been implemented for just over a year. The program is still ramping up with pharmacists continuing to undergo training and certification to dispense emergency contraception. It is still too soon to assess the impact of this policy.

While we found that very few of the men and women we surveyed had direct personal experience with emergency contraception, those who did would recommend it to others. They did not report problems in obtaining the pills and most got it from a clinic or a doctor. Only a small fraction obtained it directly from the pharmacy, so it is impossible to tell how well "behind-the-counter" access to emergency contraception from pharmacies is working from this survey.

One of the most notable findings is the disconnect between health care providers and patients about emergency contraception. Only a fraction of women and men have discussed emergency contraception with their health care providers. Even among those who had visited the doctor in the past year, very few report that they have discussed emergency contraception with their physician. Nonetheless, health care providers are trusted sources of information for most Americans and a large majority of respondents, men and women, report that they would seek information from their doctors or clinics if they wanted to learn more about emergency contraception. There is a role for the health care community in educating the general public about the availability of emergency contraception.

Most of the respondents we surveyed approve of the use of emergency contraception in a variety of scenarios: three-quarters approve of emergency contraception use in the case of birth control failure and nearly six in ten approve in the case of unprotected sex. Teens and adults overwhelmingly approve of emergency contraception use in the case of rape or incest. Fewer than one in five say that they have a religious or moral objection to the use of emergency contraception. These findings indicate that broad support for emergency contraception is likely once people are informed about this method.





Additional copies of this report (#7036) are available on the Kaiser Family Foundation's website at www.kff.org.

The Kaiser Family Foundation is a non-profit, private operating foundation dedicated to providing information and analysis on health care issues to policymakers, the media, the health care community, and the general public. The Foundation is not associated with Kaiser Permanente or Kaiser Industries.

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Agenda Item E

New Consumer Brochure and Public Education Campaign from FDA

Memorandum

To: Communication and Public Education Committee Date: March 10, 2004

From: Board of Pharmacy – Virginia Herold

Subject: New Consumer Fact Sheet from the FDA

The federal Food and Drug Administration recently published a new consumer brochure on taking OTC medications. This brochure is provided on the next pages -- "The best way to take your over-the-counter pain reliever? Seriously."

This brochure is part of a larger public information campaign established by the FDA this year. The related materials are provided as well.

Before using any medicine, remember to think SAFER:

Speak up

Ask questions

Find the facts

Evaluate your choices

Read the label

The best way to take your over-the-counter pain reliever?
Seriously.





U.S. Department of Health and Human Service



U.S. Department of Health and Human Services Food and Drug Administration

1-888-INFO-FDA • www.fda.gov/cder

DHHS Publication No. FDA03-1530A

ver-the-counter (OTC) pain relievers/fever reducers (the kind you can buy without a prescription) are safe and effective when used as directed. However, they can cause serious problems when used by people with certain conditions or taking specific medicines. They can also cause problems in people who take too much, or use them for a longer period of time than the product's *Drug Facts* label recommends. That is why it is important to follow label directions carefully. If you have questions, talk to a pharmacist or health care professional.

What are pain relievers/fever reducers?

There are two categories of over-the-counter pain relievers/fever reducers: acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs). Acetaminophen is used to relieve headaches, muscle aches and fever. It is also found in many other medicines, such as cough syrup and cold and sinus medicines. OTC NSAIDs are used to help relieve pain and reduce fever. NSAIDs include aspirin, naproxen, ketoprofen and ibuprofen, and are also found in many medicines taken for colds, sinus pressure and allergies.

Drug Facts Active ingredient (in each tablet) Purposes lbuprofen 200 mgPain reliever/Fever reducer Uses temporarily relieves minor aches and pains due to: m headache **■** backache ■ the common cold ■ minor pain of arthritis **■** toothache menstrual cramps m muscular aches m temporarily reduces fever Warnings Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: m hives im facial swelling masthma (wheezing) mashock Stomach bleeding warning: Taking more than recommended may cause stomach bleeding. Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding. Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer

How do I use pain relievers/ fever reducers safely?

These products, when used occasionally and taken as directed, are safe and effective. Read the labels of all your over-the-counter medicines so you are aware of the correct recommended dosage. If a measuring tool is provided with your medicine, use it as directed.

What can happen if I do not use pain relievers/fever reducers correctly?

Using too much acetaminophen can cause serious liver damage, which may not be noticed for several days. NSAIDs, for some people with certain medical problems, can lead to the development of stomach bleeding and kidney disease.

What if I need to take more than one medicine?

There are many OTC medicines that contain the same active ingredient. If you take several medicines that happen to contain the same active ingredient, for example a pain reliever along with a cough-cold-fever medicine, you might be taking two times the normal dose and not know it. So read the label and avoid taking multiple medicines that contain the same active ingredient or talk to your pharmacist or health care professional.

Drug Facts Active ingredient **Purposes** (in each caplet) Aspirin 500 mg......Pain reliever/fever reducer **Uses** for the temporary relief of: headache · pain and fever of colds · muscle pain · menstrual pain toothache · minor pain of arthritis Warnings Reye's syndrome: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be

toothache

Why is it important to know that all these medicines contain acetaminophen?



Because too much can damage your liver.

Acetaminophen is an active ingredient found in more than 600 over-the-counter and prescription medicines, such as pain relievers, cough suppressants and cold medications. It is safe and effective when used correctly, but taking too much can lead to liver damage. Different medicines contain different amounts, so follow dosage directions carefully. And don't take more than one acetaminophen product a day without first speaking to a health care professional. To learn more, call 1-888-INFO-FDA or visit www.fda.gov/cder. Read the label. Know the active ingredients in your medicines.



U.S. Department of Health and Human Services
Food and Drug Administration



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FDA Consumer magazine January-February 2003 Issue Pub No. FDA 03-1331C

This article originally appeared in the January-February 2003 FDA Consumer and contains revisions made in November 2003.





Use Caution With Pain Relievers

Acetaminophen is a safe and effective pain reliever that benefits millions of consumers. However, taking too much could lead to serious liver damage. The drug is sold under brand names such as Tylenol and Datril, but it is also available in many cough and cold products and sleep aids, and is an ingredient in many prescription pain relievers. The Food and Drug Administration warns consumers that all over-the-counter pain relievers should be taken with care to avoid serious problems that can occur with misuse.

Acetaminophen can cause liver injury through the production of a toxic metabolite. The body eliminates acetaminophen by changing it into substances (metabolites) that the body can easily eliminate in the stool or urine. Under certain circumstances, particularly when more acetaminophen is ingested than is recommended on the label, more of the harmful metabolite is produced than the body can easily eliminate. This harmful metabolite can seriously damage the liver.

The signs of liver disease include abnormally yellow skin and eyes (jaundice), dark urine, light-colored stools, nausea, vomiting, and loss of appetite. The signs can be similar to flu symptoms and may go unnoticed for several days if consumers believe their symptoms are related to their initial illness. Serious cases of liver disease may lead to mental confusion, coma, and death.

To avoid accidental overdosing, it's very important not to take more than the recommended dose on the label. Also, you should not take acetaminophen for more days than recommended, or take more than one drug product that contains acetaminophen at the same time. Consumers should be aware that taking more than the recommended dose will not provide more relief.

If you're taking a prescription pain medicine, check with your doctor first before taking OTC acetaminophen. The prescription pain medicine may contain acetaminophen. Acetaminophen is also available in combination with other OTC drug ingredients. So, you need to check the labels of other OTC drug products for the ingredient. In some cases of accidental acetaminophen overdose, it appears that consumers used two or more acetaminophen-containing products at the same time.

Some individuals appear to be more susceptible to acetaminophen-induced liver toxicity than others. People who use alcohol regularly may be at increased risk for toxicity, particularly if they use more than the recommended dose. Further research needs to be conducted in alcohol users to determine what factors make some alcohol users more susceptible to liver injury than others.

Parents should be cautious when giving acetaminophen to children. For example, the infant drop formula is three times more concentrated than the children's suspension. It's important to read drug labels every time you use a drug and to make sure that your child is getting the children's formula and your infant is getting the infants' formula.

Consumers should also know that there is a potential for gastrointestinal bleeding associated with the use of aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and naproxen. Aspirin is sold under brand names such as Bayer and St. Joseph's. Ibuprofen is sold under names such as Advil and Motrin. Naproxen is sold under the name Aleve. There are generic versions available for all of these products, as well.

The risk for bleeding is low for those who take these products intermittently. For those who take the products on a daily or regular basis, the risk is increased, particularly for those over 65 years of age or those who take corticosteroids (such as prednisone). Those who use hormone therapy (estrogens and progestins) for post-menopausal symptoms or birth control do not have an increased risk for bleeding.

In addition, consumers should ask health care providers about NSAID use if they have kidney disease or are taking diuretics (fluid pills).

The FDA is proposing new labeling that will inform consumers of the risk of liver toxicity from products containing acetaminophen, the risk of GI bleeding from the use of products containing NSAIDs, and factors that may increase these risks. The proposed new labeling will also better inform consumers about the ingredients contained in these products. In the meantime, read labels carefully, be sure you are getting the proper dose, and check with your health care provider to be sure that you can use these drugs safely.

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FDA Office of Public Affairs FDA Consumer Magazine



U.S. Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

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Health Hints: Use Caution with Pain Relievers

(NAPS) -- Pain relievers, when used correctly, are safe and effective. Millions of people use these n using them according to the label directions can have serious consequences.

The U.S. Food and Drug Administration (FDA) wants you to benefit from your medicines and not be should know the active ingredients and directions of all your medicines before you use them.

Over-the-counter (OTC) medicines list all their active ingredients on the package. For prescription comes with your prescription lists the active ingredients contained in the medicine.

Many OTC medicines sold for different uses have the same active ingredient. Also, active ingredien can be ingredients in prescription medicines. For example, a cold-and-cough remedy may have the sas a headache remedy or a prescription pain reliever.

There are basically two types of OTC pain relievers. Some contain acetaminophen and others contain inflammatory drugs (NSAIDs). These medicines are used to relieve the minor aches and pains assoc

- headaches
- colds
- flu
- arthritis
- toothaches
- menstrual cramps

These medicines are also used to treat migraine headaches, and to reduce fever.

Acetaminophen is a very common pain reliever and fever reducer. Taking too much of this active in liver damage. The risk for liver damage may be increased if you drink three or more alcoholic drink acetaminophen-containing medicines.

NSAIDs are common pain relievers and fever reducers. Examples of OTC NSAIDs are aspirin, ibut sodium, and ketoprofen. There are some factors that can increase your risk for stomach bleeding:

• if you are over 60

- taking prescription blood thinners
- have previous stomach ulcers or
- other bleeding problems

If you have any of these factors, you should talk to your Doctor before using NSAIDS.

NSAIDs can also cause reversible damage to the kidneys. The risk of kidney damage may increase i

- people who are over 60
- people who have high blood pressure, heart disease or pre-existing kidney disease
- people who are taking a diuretic

The FDA recommends that you talk with your healthcare professional if you have questions about u before using it in combination with other medicines -- either OTC or prescription medicine.

You can learn more about what medicines are right for you by reading the label carefully and talking professional or pharmacist.

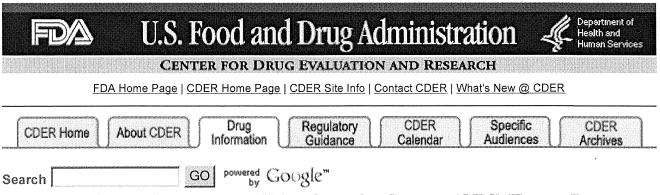
For more information, visit http://www.fda.gov or call 1-888-INFOFDA.

↑ Back to Top ■ Back to Analgesics

Date created: January 22, 2004

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FDA/Center for Drug Evaluation and Research



Questions and Answers on Using Over-the-Counter (OTC) Human Drug Products Containing Analgesic/Antipyretic Active Ingredients Safely

1. What is the Food and Drug Administration (FDA) announcing today?

The Agency is announcing today:

- A national consumer education campaign to help consumers understand how to safely use OTC pain relievers (analgesics) and fever reducers (antipyretics).
- The important educational role healthcare professionals can play in educating consumers in the safe use of these products.

2. What prompted this campaign?

In September 2002 FDA's Non-Prescription Advisory Committee (NDAC) held a public meeting to review the safety and labeling of certain OTC drug products such as acetaminophen, aspirin, and nonsteroidal anti-inflammatory drug (NSAIDs). Specifically, the committee reviewed cases of severe liver injury associated with the use of acetaminophen. They also reviewed cases of stomach bleeding and kidney injury related to the use of aspirin and NSAIDs. The committee recommended changes to the labels of these products to better inform consumers about the ingredients in the products and possible serious side effects with improper use. NDAC also recommended that FDA take a more active role in the education of consumers and health providers about the safe use of these products.

3. How do consumers take these medications safely?

You can take these medications safely by carefully reading the directions and by understanding what drugs are in the products you take. People can take too much acetaminophen either by not following directions or by taking products at the same time that both contain acetaminophen. Be sure and read the directions.

For NSAIDs, carefully read the label and make sure you do not have a health condition that would increase your risk. Aspirin and other NSAIDs can cause stomach bleeding. Although it is rare for these events to occur when using OTC doses and for short periods of time, some people do develop bleeding. You have an increased risk if you:

- have a previous history of stomach bleeding,
- are over the age of 60,
- drink three or more alcoholic drinks a day,
- take steroid medications, or take other NSAID medications.

4. What does NSAID mean?

Nonsteroidal anti-inflammatory drugs are often referred to as NSAIDs. This is a group of drugs that include products such as ibuprofen, naproxen and aspirin. NSAIDs are taken to reduce minor aches and pains, headaches and fevers.

5. Are these pain relievers safe to use?

Pain reliever and fever reducer drug products have been available for many years without a prescription. These products are safe and effective when used by consumers properly. The FDA believes that consumers need to know that pain relievers or fever reducers can cause serious side effects when used improperly. FDA urges people to read the labels of all the OTC medicines they take to know how to take them properly.

6. Where can I find more information on this?

You can find out more information by reading the FDA Consumer article "<u>Use Caution with Pain Relievers</u>". You can also ask your pharmacist or healthcare provider if you have questions about using OTC medicines with your prescription medicines.

If you have further questions regarding any medications, please contact the Center for Drug's Division of Drug Information at: 888-INFO.FDA (888-463-6332), or email us at: druginfo@cder.fda.gov.

Date created: 1/22/2004

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FDA/Center for Drug Evaluation and Research

Agenda Item F

Update on the Board's Public Outreach Activities

Memorandum

To: Communication and Public Education Committee Date: March 10, 2004

From: Board of Pharmacy – Virginia Herold

Subject: Public Outreach Activities

The board strives to provide information to licensees and the public. To this end, it has a number of consumer materials to distribute at consumer fairs and strives to attend as many of these events as possible, where attendance will be large and staff is available.

The board has developed a PowerPoint presentation on the board containing key board policies and pharmacy law. This is a continuing education course, typically provided by a board member and a supervising inspector. Questions and answers typically result in a presentation of more than two hours, which usually are well-received by the individuals present. The board also staffs an information booth at the two major pharmacist associations' annual meetings, where a number of licensees can meet with staff one-on-one.

Since the beginning of the year, the board has begun providing presentations on SB 151 and the new requirements for prescribing and dispensing controlled substances in California. A copy of this presentation is provided at the end of this section.

Public outreach activities performed since the January 21, 2004 Board Meeting:

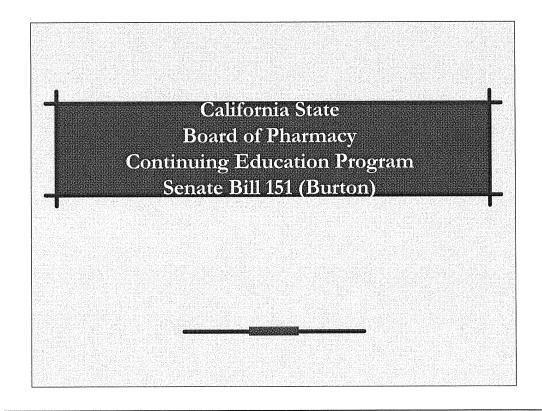
- Board staff presented information on SB 151 to 15 investigators at a FBI Drug Diversion Meeting in Northern California on January 26, 2004.
- ➤ Board inspectors staffed a booth at Outlook 2004, the annual meeting of the California Pharmacists Association. Additionally, Board members and staff provided information on the new examination structure, new pharmacy law and board operations as part of the published program events.
- ➤ Board President Jones and staff presented "Law Update 2004" (the board's CE program) to 125 students and pharmacists at USC School of Pharmacy, February 5, 2004.
- ➤ Board Member Ruth Conroy presented information on SB 151 at a session held by the San Francisco Health Plan P & T Committee in February.
- ➤ Board staff present information to 125 UCSF students on legislative changes to Pharmacy Law on February 24.
- ➤ Board Member Ruth Conroy provided information about board activities at a February 27th Circle of Advisors Meeting of the Pharmacy Access Partnership

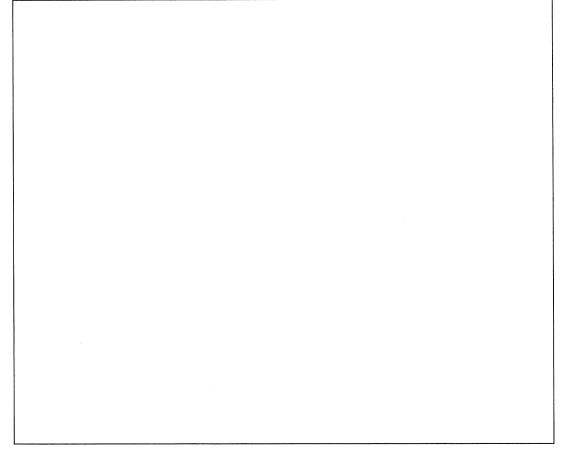
- Board staff presented information to 125 UCSF students on the Board of Pharmacy on March 2, 2004.
- ➤ Board staff presented information on SB 151 to 60 people at the California Coalition for Compassionate Care Train the Trainers meeting in Sacramento on March.
- > Staff presented information on SB 151 to 60 members at the Northern California Pain Coalition meeting on March 8 to 60, a "train the trainer" event.
- Board staff provided a training session to complaint staff of the Medical Board of California on March 17.

Scheduled presentations in the future

- ➤ Board Member Ken Schell will present information to the San Diego Association for Healthcare Risk Management on March 23.
- ➤ Board Staff will present information on SB 151 to physicians and pharmacists as part of a noon CE program offered by teleconference on March 23.
- ➤ Board staff will present information on SB 151 to the California Coalition for Compassionate Care on March 29.
- Board Members and staff will present the board's CE program at a May 13 meeting of the San Diego Pharmacists Association Meeting.
- ➤ Board staff will present information on the new examination process for pharmacists to 200 UOP students on May 11.
- ➤ Board presentation scheduled or May 19th at USC's School of Pharmacy.
- ➤ The board's CE presentation will be provided at a July 22 meeting of the Santa Barbara Pharmacists Association.
- ➤ The board's CE program will be presented at a future Catholic Healthcare West meeting
- Supervising Inspector Robert Ratcliff has been asked to give the keynote address at CSHP's 2004 Seminar in Long Beach, November 2004
- ➤ Board staff will present an "Update and What's New in Pharmacy Compounding" at the CSHP's 2004 Seminar in Long Beach in November 2004.

The board provided a number of consumer materials to the department for handouts during outreach events for seniors and young people during National Consumers Week in February.





Put Patients First

SB 151 shifts complexity away from the patient onto the health professionals.

Senate Bill 151 (Burton)

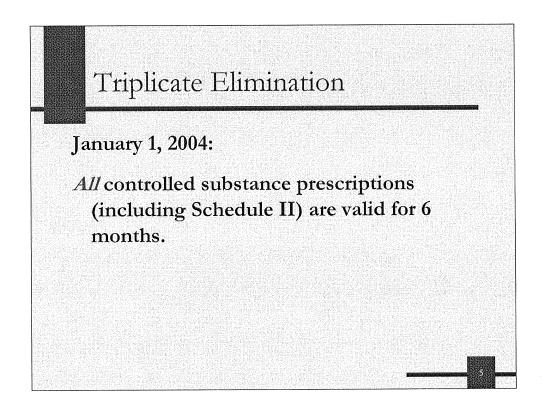
Legislative Intent

- 1. *Increase* patient access to appropriate pain medication and prevent the diversion of controlled substances for illicit use.
- 2. Provide that the forms required by the act for controlled substance prescriptions may be used to prescribe *any prescription drug* or device.

These intent statements are taken directly from uncodified intent language included in Senate Bill 151.

Overview of SB 151

Eliminates Triplicates
New Prescription Forms
Simplifies Prescribing Rules
Retains Terminal Illness Exemption
Makes CURES Permanent
Extends CURES to Schedule III



Previous to this bill Schedule II controlled substance prescriptions were only valid for 14 days.

The DEA allows prescribers to write multiple CII prescriptions at a single office visit with instructions not to fill before a certain date. For example, the prescriber could write a prescription for a one month supply of oxycodone on six scripts with instructions to the pharmacy to not fill the script before the first of each month ("Do not fill before March 1, April 1, May 1, etc.). This reduces the number of office visits required for patients on chronic CII drug therapy. The Board of Pharmacy accepts this practice as well.

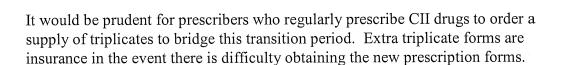
Triplicate Elimination cont'd

July 1, 2004:

Triplicate is *not* required for Schedule II prescriptions.

Prescribers *may* use new security prescription forms for Schedule II prescriptions.

New triplicate forms may not be ordered.



Printers have indicated that once they have initially verified the prescriber's credentials, orders for additional forms can be filled in 1-2 days.

January 1, 2005 All written controlled substance prescriptions (Schedules II-V) must be on security prescription forms. Fax and oral prescriptions for Schedules III-V are allowed.

If faxed, the new prescription forms will result in the pharmacy receiving a prescription with "void" on the face. The Board of Pharmacy recommends that prescribers faxing prescriptions use plain paper prescriptions for that purpose. A pharmacy that receives a prescription with this "void" faxed prescription can fill it if they confirm the prescription with the prescriber's office.

New Prescription Forms

Forms obtained from approved *private printers*.

Forms may be ordered in any quantity.

Forms may be ordered in any format.

Forms are not serialized.

Forms are not multi-copy.

Forms have required security features.

The Board of Pharmacy and the Department of Justice must jointly approve the printers who sell the new prescription forms.

The Board of Pharmacy and other appropriate licensing boards will have the name and contact information for the approved printers on its website.

SB 151 only specifies the minimum security features on the forms. Prescribers may order forms in any format (size, multiple copy, etc.) that they desire. Logos and other customizations are permitted.

Forms may be customized for organizations using electronic medical record systems or electronic prescribing systems. The forms must contain the required security features when purchased from the printer but computer printers can fill out the form leaving only the signature and date to be written by the prescriber.

New Prescription Forms cont'd

Security Features:

Latent Void

Chemical Void

Thermo-Chromic Ink

Watermark

Microprinting

Preprinted Prescriber Information

Quantity Check-off Boxes

The new forms must include a lot number representing each shipment to the prescriber and each script in that lot must be numbered beginning at "1". Taken together these numbers do constitute a unique identifier for each prescription form, but this information is not tracked by CURES. The numbers need not be located next to one another on the script.

Each form must include a description of the security features included on the form (the logo is printed in thermochromic ink, latent void protection is included, micro-printing is in this location, etc.).

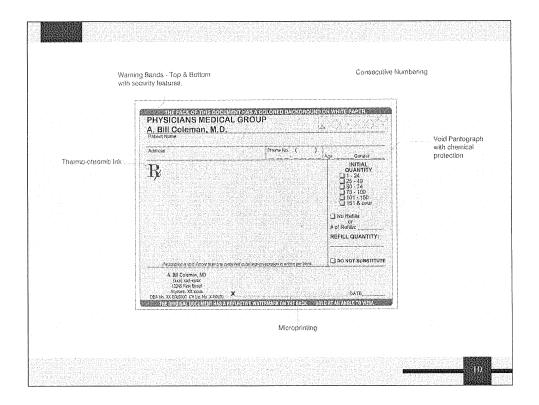
Latent Void – if copied the copies will come up with "void" on them.

Chemical Void – if exposed to ink solvents (e.g. acetone) the original prescription will come up "void."

Thermo-Chromic Ink - a single feature must be printed in this ink which changes color when exposed to heat. The feature will return to the original color when it cools.

Watermark – this requires a printed watermark on the back of the prescription that reads "California Security Prescription." This is not a watermark in the paper but a printing process.

Microprinting – this feature prints very fine and small text that will appear as a solid line if copied or scanned.

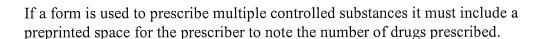


This sample form is missing the description of security features that is required to be printed on the form.

Multiple Prescriptions

SB 151 requires one of two statements on each prescription form.

- 1. "Prescription is void if more than one controlled substance is written per blank."
- 2. "Prescription is void if the number of controlled substances prescribed is not noted."



Prescribers must decide when ordering forms if they wish to prescribe multiple controlled substances on a single form and have the printer produce the appropriate form.

New Prescription Forms cont'd

Institutional Forms:

Can Be Used In Licensed Health Facilities
Do Not Require Preprinted Prescriber Info
Require Preprinted Facility Info
Ordered by "Designated Prescriber"
Issued by "Designated Prescriber"
Records Maintained by "Designated
Prescriber"

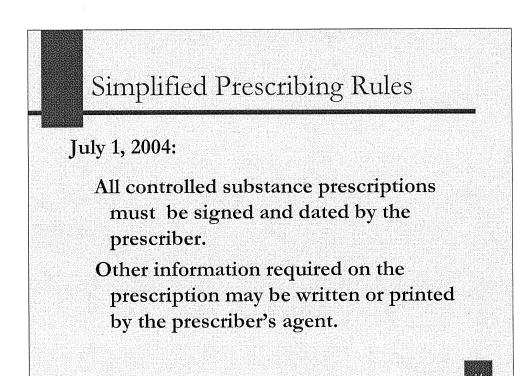
This institutional form was created to allow hospitals and other health facilities to provide institutionally appropriate forms to temporary physicians, residents, and other short term providers. Prescribers regularly working in the facility should each have their own forms provided and not use these institutional forms.

Designated Prescriber

- **♯** May be any prescriber eligible to order forms.
- ➡ Designated prescriber's name, license number and DEA number are preprinted on the forms.
- ♯ Designated Prescriber must keep records of the prescribers to whom the forms are issued.
- ♯ Records must include the name, license number, DEA number and the quantity of forms issued.
- ♯ Records must be maintained for three years.



The designated prescriber does not need to personally hand out the institutional forms. That task may be delegated to other facility staff. However, the designated prescriber will be held responsible regardless of the system used to provide the forms.



The only elements of the prescription that must be written by the prescriber is the date the prescription is issued and the signature of the prescriber.

Terminal Illness Exemption

Prescribers may continue to use normal prescription forms when ordering Schedule II drugs for terminally ill patients.

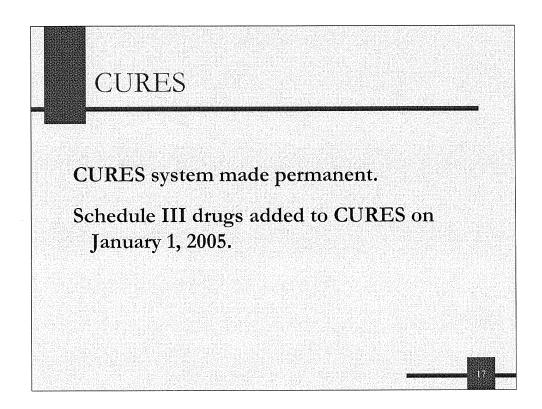
Note Section 11159.2 on Prescription.

Same Prescribing Rules as for all other controlled substance prescriptions.

The need for this exemption should diminish over time as all prescribers acquire the new prescription forms and will therefore be able to prescribe CIIs.

Special Care Settings

- ♯ SNF, INT, HH, & Hospice patients can receive Schedule II prescriptions faxed or phoned into a pharmacy serving those patients. Effective July 1, 2004.
- ➡ "Pharmacy Generated Triplicate" is replaced by a form of the pharmacy's design effective July 1, 2004.
- ♯ Health and Safety Code 11167.5



CURES = Controlled Substance Utilization Review and Evaluation System

CURES was established to test electronic monitoring of CII prescribing as an alternative to the triplicate form. The system has been collecting information since 1997 as a pilot project. SB 151 makes this system permanent and expands the data collected to include CIII information.

Electronic monitoring allows law enforcement and regulatory agencies to more efficiently identify potential drug diversion.

Currently, the CURES system logs approximately 3.5 million CII prescriptions per year and the addition of CIII information is expected to increase that by up to a factor of 10.

CURES is funded jointly by the affected regulatory boards and the Department of Justice.

What is CURES

CURES collects CII prescription information (patient, prescriber, pharmacy, drug, amount, strength, etc.) from pharmacies.

This information is submitted in electronic format on a monthly basis.

The information is aggregated into a statewide database used by law enforcement and regulatory agencies.

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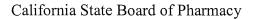
Prescribers dispensing CII and CIII drugs will have to submit the same information to the CURES system. For CII dispensing this reporting begins on July 1, 2004. For CIII information the reporting begins on January 1, 2005.

Patient Activity Reports

Prescribers and pharmacists can obtain "patient activity reports" from the Department of Justice.

The request form can be found at:

http://ag.ca.gov/bne/content/trips.htm



Prescribing Privileges

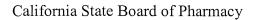
- **♯** Physicians
- **♯** Physician Assistants
- **♯** Nurse Practitioners
- **♯** Nurse Midwives
- **■** Dentists
- **¥** Veterinarians
- **♯** Osteopaths
- **♯** Podiatrists
- **♯** Optometrists

Schedule II Drugs (Examples)

- **■** Morphine
- **♯** Oxycontin
- **♯** Demerol
- **♯** Dilaudid
- **♯** Ritalin
- **♯** Fetanyl
- **■** Methadone

Schedule III Drugs (Examples)

- **▼** Vicodin
- # Tylenol with Codeine
- **♯** Anabolic Steroids
- **♯** Ketamine
- **♯** Dronabinol

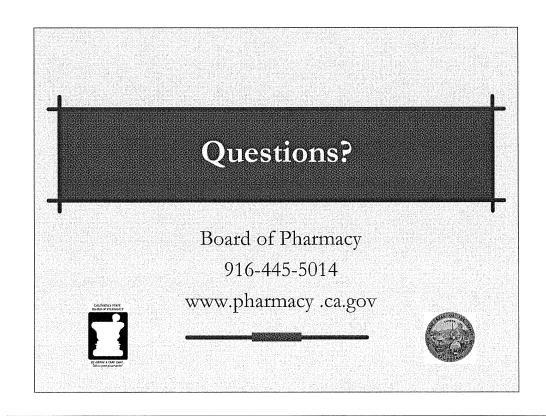


Schedule IV Drugs (Examples) # Valium # Xanax # Darvon # Halcion # Ambien # Talwin # Sonata

Dangerous Drugs v. Controlled Substances

Dangerous Drugs = Any Drug that Requires a Prescription

Controlled Substances =
Dangerous Drugs that have
Abuse Potential





Agenda Item G

Strategic Plan Review and Update

Memorandum

To: Communication and Public Education Committee Date: March 12,2004

From: Board of Pharmacy – Virginia Herold

Subject: Strategic Plan Update

At the April board meeting, the board will review and revise its strategic plan for the next year. Each committee has been directed to review its strategic goals and identify any necessary changes.

So during this committee meeting, the committee will review its strategic goals for 2004/05. A copy of the January 2004 strategic plan status report is provided in this section.

As background: two years ago, the board substantially revised its strategic plan, and last year, the goals were reformatted to fit into a new structure.

The committee could also use this as an opportunity to include the following tasks into its strategic plan to reflect several activities initiated in the last year.

Objective 4.1

Add as new task 5: Evaluate the need for public education for patients who need to request prescription labeling in a language other than English.

Note: At the last committee meeting, a discussion took place regarding the need for patients to understand that they can ask to have their prescription containers labeled in a language other than English, if this will aid them. A discussion was planned for the January board meeting, but the individuals who brought the matter before the board could not attend the meeting.

Objective 4.2

Add as new task 5: Create consumer fact sheet series in conjunction with California schools of pharmacy on topics of interest

Add as new task 6: Create public education activities to educate prescribers, dispensers, patients and law enforcement about changes in law regarding dispensing of controlled substances.

Strategic Plan Status Report Second Quarter 2003-04 Communication and Public Education Committee

Goal: 4: Provide relevant information to consumers and licensees.

Outcome: Improved consumer awareness and licensee knowledge.

Objective 4.1:	Develop 10 communication venues to the public by June 30, 2005.
Objective 4.1.	bevelop to communication vendes to the public by built 50, 2005.
	Number of communication venues developed to the public
Measure:	
Tasks:	 Convert <i>Health Notes</i> articles into consumer columns or fact sheets for wide dissemination to the public. Develop and update public education materials.
	August 2003: Board finalizes purchasing drugs from Canada brochure and revises discount drugs available to Medicare beneficiaries.
	October 2003: Emergency Contraception fact sheet has suggested revisions to reflect new treatment guidelines. Four brochures targeted for translation into Spanish (Emergency Contraception, Purchasing Drugs for Less, Purchasing drugs from foreign countries and discount drug prices available to Medicare Beneficiaries)
	3. Maintain a vigorous, informative Web site. July 2003: Materials for public meetings, including board meetings and most committee meetings placed on Web site for downloading by the public.
	August 2003: New staff person assigned to revamp Web site, who completes Web site development training September 2003: Board completes pilot testing for integration of enforcement information into license verification portion of Web site. The board will add this look-up feature before January 1, 2004.
	October 2003: SB 361 enacted which will authorize verification of licensure when info is downloaded from the board's Web site. November 2003: Board adds information regarding new exam procedures and requirements to applicants for a pharmacist license
	December 2003: Enforcement status data undergoes pilot testing before full implementation and activation into license verification section of Web site. Address of records of board licensees added to Web site January 2004: Board updates Pharmacy Law and Index to reflect
	new laws 4. Sponsor "Hot Topics" seminars to the public.
	July 2003: This series, sponsored by UCSF, the Department of Consumer Affairs and the board, concluded in May 2003. All parties are interested in resuming this project if staff are available to coordinate.

Status Report 2: January 2004

	The first of consumer fact sheets developed from this series is drafted for board review by the Department of Consumer Affairs.
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Objective 4.2:	Develop 10 communication venues to licensees by June 30, 2005.
	Number of communication venues developed to licensees
Measure:	realiser of communication vehicle developed to memore
	1. Publish <i>The Script</i> two times annually.
Tasks:	October 2003: The Script is published and mailed to all pharmacies. CPhA's Education Foundation will print and mail the newsletter to all California pharmacists November 2003: CPhA's Education Foundation mails October The
	Script to all pharmacists.
	January 2004: Articles for the next issue of The Script are completed and sent for legal review. Planned publication date is February.
	2. Publish one <i>Health Notes</i> annually.
	September 2003: Discussions begin to coordinate a major revision to "Pain Management" Health Notes, updating treatment information as well as new requirements for prescribing and dispensing controlled drugs in California enacted by SB 151, which will take effect in a series of stages throughout 2004. November 2003: Authors for "Pain Management" selected and commit to writing articles, which are due in late January.
	3. Develop board-sponsored continuing education programs in pharmacy law and coordinate presentation at local and annual professional association meetings throughout California. July 2003: Board presents PowerPoint continuing education program to 35 MediCal staff in Los Angeles and 60 pharmacists at local association meeting in Santa Barbara.
	September 2003: presentation to 40 pharmacists at the Long-Term Care Academy. Board Member Jones attends the Indian Pharmacist Association Meeting October 2003: Presentation and information booth provided at CSHP's Seminar 2003 December 2003: Board provides continuing education to 80
	 pharmacists at Coachella Valley local association January 2004: Board provides compounding pharmacy information to 25 health directors of large hospital chain in U.S. 4. Maintain important and timely licensee information on Web site. July 2003: All information packets for public meetings of the board placed on Web site in addition to agendas October 2003: The October 2003 The Script added to Web site November 2003: The board places information about new pharmacist licensure examinations on Web site January 2004: Web page modified to make it easier to find
	pharmacist licensure examination information

Licensure verifications can be performed by printing license verification information from the Web site, eliminating need to obtain this directly from board	
Participate in 20 forums, conferences and public education events by June 30, 2005.	
Number of forums participated	
1. Participate in forums, conferences and educational fairs. August 2003: Board staffs an information booth at Sacramento's Consumer Health Fair, co-hosted by Kaiser, AARP, Area 4 Agency on Aging and Congressman Matsui: September 2003: Board President Jones attends NABP's District VII and VIII annual meeting October 2003: Board staffs an information booth at CSHP Seminar 2003 Board staffs an information booth at Los Angeles County Health Fair and Senior Festival, over 2,000 people attend. Board staffs an information booth at Sacramento's Healthy Aging Summit	
Respond to 100 percent of information requests from governmental agencies regarding board programs and activities. Percentage response to information requests from governmental	
agencies	
 By June 1, 2004, submit report to Legislature on statutory requirements for remedial education after four failed attempts on the California pharmacist exam. Provide information to legislators regarding board implementation of statutory requirements. Provide agency statistical data information to the department. Sept. 2003: Board submits data to department as required. Nov. 2003: Board provides information to department on impact of budget reductions in terms of funding and staff in response to request from Senate Business and Professions Committee Board provides information to department on the Bilingual Services Program Survey due September 15, 2003. September 2003: data provided January 2004: All staff collect data for survey of public contacts by the language of the individual Department of Consumer Affairs, Internal Audit of the Board released March 2003 as part of Sunset Review October 2003: Board compiles 180-day post audit report to the department Regulation Summary Report of all regulations enacted from 1999-2003, pursuant to Executive Order S-2-03 January 2004: Report compiled and submitted timely Review of board operations, procedures, procedure manuals, 	

Status Report 2: January 2004

	to Executive Order S-2-03 January 2004: Report compiled and submitted timely 8. Board meets with delegation from China Zhejiang Provinical Drug Administration at request of this agency in December 2003
Objective 4.5	Respond to 100 percent of public information requests regarding board programs and activities.
Measure:	Percentage response to information requests from the public
	Respond to public information requests.
Tasks:	July – Oct. 2003: the board received 340 public inquiries and four subpoenas. Nearly 80 percent of the public inquiries were responded to within 10 days, and all four of the subpoenas were responded within required timeframes. Oct. – Dec. 2003: the board received to 253 public inquiries and three subpoenas. Nearly 65 percent of the public inquiries were responded to within 10 days, and all three of the subpoenas were responded to within required timeframes.

Status Report 2: January 2004